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Henry Daniell

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EXAMINER

KUBELIK, ANNE R

ART UNIT

PAPER NUMBER

1638

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/519,821	<b>Applicant(s)</b> DANIELL, HENRY	
	<b>Examiner</b> Anne R. Kubelik	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 11 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11, 12, 15-23, 25-27, 30-33 and 35-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11, 12, 15-23, 25-27, 30-33 and 35-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 January 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 1-9, 11-12, 15-23, 25-27, 30-33 and 35-42 are pending.
2. The objection to claim 26 under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only is withdrawn in light of Applicant's amendment of the claim.
3. The objection to claims 32-33 and 38 because of informalities is withdrawn in light of Applicant's amendment of the claims.
4. The rejection of claims 23-24, 32 and 38 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention is withdrawn in light of Applicant's amendment of the claims.

### ***Claim Objections***

5. Claims 32, 35 and 42 are objected to because of the following informalities:  
  
Claim 32 is objected to because there is an improper article before "vector" in line 5.  
  
Claim 35 is objected to because "from" is misspelled in line 5.  
  
In claim 42 --the group consisting of-- should be inserted after "from" in line 1.

### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims 3-5, 32 and 40-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 3 is indefinite in its recitation of “in light and in.” A word appears to be missing from the claim.

Claim 32 lacks antecedent basis for the limitation “said selectable marker gene proteins” in line 6.

Claim 40 lacks antecedent basis for the limitation “said selectable marker gene proteins” in line 5.

### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-4, 7, 16-17, 20-23, 26-27, 30-33, 35-37 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Daniell (WO 99/10513) taken with the evidence of the instant specification. The rejection is repeated for the reasons of record as set forth in the Office action mailed 11 July 2007, as applied to claims 1-4, 7, 13-14, 16-17, 20-25, 27-37 and 39.

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Applicant's arguments filed 11 January 2008 have been fully considered but they are not persuasive.

Daniell discloses a plastid transformation vector comprising a first flanking sequence (rbcL or 16S/trnI), a promoter (Prn or PatpB), a selectable marker (aadA, which encodes an aminoglycosidase), a heterologous DNA coding for a foreign gene (EPSPS, EG121, mGFP4, hph, CryIIA), a 3' UTR (psbA 3'), and a second flanking sequence (ORF512 or trnA) (Fig. 2-3, 5-8). Both sets of flanking sequences are conserved in the plastid genome of higher plant species (pg 20, lines 20-34) and are transcriptionally active spacer regions (pg 9, lines 6-22). The instant specification teaches that the Prn promoter is functional in green and non-green plastids, that is, in light and dark (pg 39, lines 4-7), and that the psbA 3' UTR provides transcript stability to the DNA coding for a foreign gene (pg 44, line 32, to pg 45, line 1).

Daniell also discloses Arabidopsis plants whose plastids are transformed via their roots with the vectors (pg 50, lines 17-21). Daniell also discloses somatic embryos transformed with the vectors (pg 50, line 17, to pg 51, line 4). Further, all the plants whose plastids are transformed with these vectors in Daniell (pg 42-51) would have roots and other non-green plant parts whose plastids comprise the vector; these non-green plant parts would be capable of regenerating through somatic embryogenesis. Green or non-green plant cells transformed with the vector that are regenerated via somatic embryogenesis would be structurally identical to green or non-green plant cells, respectively, transformed with the vector that are not regenerated via somatic embryogenesis. Daniell et al discloses progeny and seeds of plants transformed with one of the vectors (pg 59, line 32, to pg 60, line 9). Growing the plant cells would express the protein of interest.

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Applicant urges that the applicant confirmed that WO 99/10513 does not teach somatic embryogenesis (response pg 11).

This is not found persuasive because hearsay is not acceptable; this needs to be presented in a Declaration. Further, it would not overcome the rejection over claims 1-4, 7, 16-17, 20-21, 23, 35-36 and 39, which are drawn to a vector, and claims 22 and 26, which are drawn to plants transformed with the vector. The rejection over claims 30 and 33 would not be overcome unless Applicant could show a difference between non-green plant cells whose plastids were transformed through somatic embryogenesis and non-green plant cells whose plastids were transformed through another means. The rejection over claim 31 would not be overcome because the only mention of somatic embryogenesis is in the preamble; the only method step is merely drawn to introducing the vector into a plant plastid. The rejection over claim 37 would not be overcome because there is no somatic embryogenesis step.

Applicant urges that the claims now specify that the vectors are species specific (response pg 11).

This is not found persuasive because the vectors taught by Daniell have flanking sequences from tobacco (pg 22, lines 12-26), which Daniell transformed (example 2). Further, the recitation that the flanking sequences are from the same species as the plant cell is an intended use limitation, and not given patentable weight in claims drawn to the vector.

10. Claims 1-4, 7, 16-23, 25-26, 30-31, 33 and 35-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Daniell et al (2001, Curr. Genet. 39:109-116) taken with the evidence of the instant specification. The rejection is repeated for the reasons of record as set forth in the Office

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action mailed 11 July 2007, as applied to claims 1-4, 7, 13-14, 16-25, 28-31, 33-39. Applicant's arguments filed 11 January 2008 have been fully considered but they are not persuasive.

Daniell et al disclose a plastid transformation vector comprising a first flanking sequence (16S/trnI), a promoter (Prn), a heterologous DNA coding for a foreign gene (aadA), a selectable marker (BADH), a 3' UTR (psbA 3'), and a second flanking sequence (trnA) (Fig. 1).

Alternately, aadA could be the selectable marker and BADH the gene of interest. Both flanking sequences are conserved in the plastid genome of higher plant species and are transcriptionally active spacer regions (paragraph spanning the columns on pg 111). The instant specification teaches that the Prn promoter is functional in green and a non-green plastids (pg 39, lines 4-7), and that the psbA 3' UTR provides transcript stability to the DNA coding for a foreign gene (pg 44, line 32, to pg 45, line 1).

Daniell et al also disclose tobacco plants whose plastids are transformed with the vector and progeny and seeds from the transformed plants (pg 112, left column, paragraph 3, to right column, paragraph 3; pg 115, left column, paragraph 2). The plants transformed with this vector would have roots and other non-green plant parts whose plastids comprise the vector; these non-green plant parts would be capable of regenerating through somatic embryogenesis. Green or non-green plant cells transformed with the vector that are regenerated via somatic embryogenesis would be structurally identical to green or non-green plant cells, respectively, transformed with the vector that are not regenerated via somatic embryogenesis. Growing the plant cells would express the protein of interest, including BADH.

Applicant urges that the applicant confirmed that Daniell et al does not teach somatic embryogenesis (response pg 11).

This is not found persuasive because this needs to be presented in a Declaration. Further, it would not overcome the rejection over claims 1-4, 7, 16-21, 23, 25, 35-36 and 39, which are drawn to a vector, and claims 22 and 26, which are drawn to plants transformed with the vector. The rejection over claims 30 and 33 would not be overcome unless Applicant could show a difference between non-green plant cells whose plastids were transformed through somatic embryogenesis and non-green plant cells whose plastids were transformed through another means. The rejection over claim 31 would not be overcome because the only mention of somatic embryogenesis is in the preamble; the only method step is merely drawn to introducing the vector into a plant plastid. The rejection over claims 37-38 would not be overcome because there is no somatic embryogenesis step.

Applicant urges that the claims now specify that the vectors are species specific (response pg 11).

This is not found persuasive because the vectors taught by Daniell have flanking sequences from tobacco (pg 22, lines 12-26), which Daniell transformed (example 2). Further, the recitation that the flanking sequences are from the same species as the plant cell is an intended use limitation, and not given patentable weight in claims drawn to the vector.

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.



12. Claims 1-4, 7, 11-12, 16-17, 20-23, 25-27, 30-33, 35-37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniell (WO 99/10513). The rejection is repeated for the reasons of record as set forth in the Office action mailed 11 July 2007, as applied to claims 1-4, 7, 10-14, 16-17, 20-25, 27-37 and 39. Applicant's arguments filed 11 January 2008 have been fully considered but they are not persuasive.

The claims are drawn to plastid transformation vectors in which one flanking sequence is a 4 kb long region comprising 16S/trnI and the other is a 4 kb long region comprising trnA/23S.

The teachings of Daniell are discussed above. Daniell does not disclose flanking sequences that are 4 kb long or comprise trnA/23S.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the plastid transformation vectors taught by Daniell to make the flanking sequences 4 kb long. One of ordinary skill in the art would have been motivated to do so because Daniell suggests using longer flanking sequences and including all or part of 16S and 23S (pg 20, lines 29-34; pg 22, lines 4-11). Flanking sequences that are about 4 kb long would be made in the optimization of vectors.

Applicant urges that the applicant confirmed that WO 99/10513 does not teach somatic embryogenesis (response pg 11).

This is not found persuasive because this needs to be presented in a Declaration. Further, it would not overcome the rejection over claims 1-4, 7, 11-12, 16-21, 23, 25, 35-36 and 39, which are drawn to a vector, and claims 22 and 26, which are drawn to plants transformed with the vector. The rejection over claims 30 and 33 would not be overcome unless Applicant could show a difference between non-green plant cells whose plastids were transformed through

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somatic embryogenesis and non-green plant cells whose plastids were transformed through another means. The rejection over claim 31 would not be overcome because the only mention of somatic embryogenesis is in the preamble; the only method step is merely directed to introducing the vector into a plant plastid. The rejection over claims 37-38 would not be overcome because there is no somatic embryogenesis step.

Additionally, Daniell's teachings would make regeneration through somatic embryogenesis obvious, given Daniell's Table II.

13. Claims 5-6 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniell (WO 99/10513) as applied to claims 1-4, 7, 11-12, 16-17, 20-23, 25-27, 30-33, 35-37 and 39 above, and further in view of Maliga et al (1999, US patent 5,877,402). The rejection is repeated for the reasons of record as set forth in the Office action mailed 11 July 2007. Applicant's arguments filed 11 January 2008 have been fully considered but they are not persuasive.

The claims are drawn to plastid transformation vectors with psbA 5'UTRs.

The teachings of Daniell are discussed above. Daniell does not disclose psbA 5' UTRs in the vectors.

Maliga et al teach a variety of plastid transformation vectors with 5' and 3'UTRs, including 5' and 3' UTRs from psbA (Fig 22B and C).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the plastid transformation vectors taught by Daniell to include the vector the psbA 5' UTR described in Maliga et al. One of ordinary skill in the art would have been motivated to do so because Maliga et al teaches that 5'UTRs, especially that of psbA, improve expression of the protein of interest (column 24, line 63, to column 25, line 49).

Applicant urges that Maliga attempted to transform rice but failed, and that their rice plant is heteroplastomic (response pg 11).

This is not found persuasive because there is no mention of an attempt to transform rice in US 5,877,402.

Applicant urges that in Khan et al that the rice plants they produced were heteroplastomic, and this was restated in Maliga 2004 (response pg 11-12).

This is not found persuasive because the rejection was not over Khan et al; Maliga 2004 could not be considered because it was not sent.

Applicant summarizes their invention, citing Sidorov1999, Ruf, 2001, Skarjinskaia 2003, Ferandez San Millan 2003, Dhingra 2004, DeGray 2001, Bogorad 2000, Daniell 2002, Devine 2004, Stern 1987, Daniell 2004, Bateman 2000, Huang 2002, and Stuab 1995 (response pg 12-18).

This is not found persuasive. Skarjinskaia 2003, Ferandez San Millan 2003, Dhingra 2004, Bogorad 2000, Devine 2004, Stern 1987, Bateman 2000 and Stuab 1995 could not be considered because they were not sent.

Applicant has not pointed to anything in Sidorov1999, Ruf, 2001, DeGray 2001, Daniell 2002, Daniell 2004, or Huang 2002 to indicate that the claims are not obvious over Daniell (WO 99/10513) further in view of Maliga et al.

Claims 1-7, 11-12, 15-21, 23, 25, 35-36 and 39 are drawn to a vector, and claims 22 and 26 are drawn to plants transformed with the vector. Daniell in view of Maliga makes these obvious; Applicant's method of transformation is not relevant to these claims. The rejection over claims 30 and 33 would not be overcome unless Applicant could show a difference between

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non-green plant cells whose plastids were transformed through somatic embryogenesis and non-green plant cells whose plastids were transformed through another means. The rejection over claim 31 would not be overcome because the only mention of somatic embryogenesis is in the preamble; the only method step is merely drawn to introducing the vector into a plant plastid. The rejection over claims 37-38 would not be overcome because there is no somatic embryogenesis step.

It appears from Applicant's arguments that several steps may be essential to the operation of the claimed method; if this is the case, these steps should be included in the method claims.

14. Claims 6 and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniell (WO 99/10513) as applied to claims 1-4, 7, 11-12, 16-17, 20-23, 25-27, 30-33, 35-37 and 39 above, and further in view of McBride et al (1999, US patent 5,925,806). The rejection is repeated for the reasons of record as set forth in the Office action mailed 11 July 2007.

Applicant's arguments filed 11 January 2008 have been fully considered but they are not persuasive.

The claims are drawn to plastid transformation vectors with the T7 gene 10 5'UTR and the rps16 3'UTR.

The teachings of Daniell are discussed above. Daniell does not disclose the T7 gene 10 5'UTR and the rps16 3'UTR in the vectors.

McBride et al teach plastid transformation vectors with the T7 gene 10 promoter and 5'UTR (column 15, line 27-47) and the use of the rps16 3'UTR (Fig 2).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the plastid transformation vectors taught by Daniell to include the T7 gene 10

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promoter and 5'UTR and the rps16 3'UTR described in McBride et al. One of ordinary skill in the art would have been motivated to do so because the T7 gene 10 promoter and 5'UTR allow regulation of expression from tissue-specific or inducible promoters in the nucleus (McBride et al, column 2, lines 42-54); additionally, the T7 gene 10 5'UTR has a strong ribosome binding site, which would improve translation of the protein of interest (column 15, line 27-47). Choice of 3'UTR, including the rps16 3'UTR, is an effective parameter that a person of ordinary skill in the art would routine optimize. Optimization of parameters is a routine practice that would be obvious for one of ordinary skill in the art to employ to best achieve the desired results.

Applicant made no arguments specific to this rejection.

15. Claims 1-4, 7, 16-17, 20-23, 26-27, 30-33, 35-37 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniell (WO 99/10513) in view of Adams et al (1999, US Patent 5,919,675) and taken with the evince of Daniell (US Patent 7,129,391).

The claims are drawn to plastid transformation vectors and a method of plastid transformation comprising transforming the plastids of a plant cell with the vector, and culturing the resulting transplastomic cell in the presence of the selection agent to allow the cell to form a somatic embryo, which is then regenerated into a transplastomic plant.

The teachings of Daniell (WO 99/10513) are discussed above. Daniell ('391, which has the same specification as WO 99/10513) shows that WO 99/10513 teaches the transformation of maize plastids (claims 72-74, 78-80, 91).

Daniell (WO 99/10513) does do not teach culturing the transplastomic cell in the presence of the selection agent to allow the cell to form a somatic embryo, which is then regenerated into a transplastomic plant.

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Adams et al teach culturing the maize cells transformed via particle bombardment in the presence of the selection agent to allow the cell to form a somatic embryo, which is then regenerated into a transformed plant (column 30, line 6, to column 34, line 7).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of producing transplastomic maize plants taught by Daniell to use a step in which the transformed maize cell is developed into a somatic embryo before regeneration into a plant as described in Adams et al. One of ordinary skill in the art would have been motivated to do so because Adams et al describe an effective method for producing fertile transformed maize plants.

### ***Double Patenting***

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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17. Claims 1, 11-12, 17, 22-23, 26, 30-31, 33, 35-37 and 39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-121 of U.S. Patent No. 7,129,391.

Although the conflicting claims are not identical, they are not patentably distinct from each other because plastid transformation vectors comprising a first flanking sequence derived from a plastid sequence, a 5' regulatory sequence, a DNA coding for a peptide of interest, a 3' regulatory sequence, and a second flanking sequence derived from a plastid sequence, and plants transformed therewith, as claimed in the issued patent, a species of the genus of plastid transformation vectors comprising a first flanking sequence, a DNA coding for a foreign gene, and a second flanking sequence, and plants transformed therewith, as claimed in the current application. Further, the methods of transforming a plant with the vector further comprising a selectable marker, , as claimed in the issued patent, make obvious the saintly vectors further comprising a selectable marker.

18. Claims 1, 11-12, 17, 22-23, 26, 30-31, 33, 35-37 and 39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,680,426.

Although the conflicting claims are not identical, they are not patentably distinct from each other because plants transformed with constricts comprising a first flanking sequence derived from a plastid sequence, a promoter, a DNAs coding for peptides of interest, a terminator, and a second flanking sequence derived from a plastid sequence, and a method of making the plants using vectors comprising a selectable marker, as claimed in the issued application, make obvious the plastid transformation vectors comprising a first flanking

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sequence, a DNA coding for a foreign gene, and a second flanking sequence, and plants transformed therewith, claimed in the instant application.

19. Claims 1, 11-12, 17, 22-23, 26, 30-31, 33, 35-37 and 39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 7,135,620.

Although the conflicting claims are not identical, they are not patentably distinct from each other because vectors and expression cassettes for plastid transformation comprising a first flanking sequence derived from a plastid sequence, a 5' regulatory sequence, a DNAs coding for a peptide of interest and selectable marker, a 3' regulatory sequence, and a second flanking sequence derived from a plastid sequence, and plants transformed therewith, as claimed in the issued patent, make obvious the plastid transformation vectors comprising a first flanking sequence, a DNA coding for a foreign gene, and a second flanking sequence, and plants transformed therewith, claimed in the instant application.

20. Claims 1, 11-12, 17, 22-23, 26, 30-31, 33, 35-37 and 39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 7,294,506.

Although the conflicting claims are not identical, they are not patentably distinct from each other because plastid transformation vectors comprising a first flanking sequence derived from a plastid sequence, a plastid promoter, a multi-gene operon encoding a biopharmaceutical protein, a chaperonin and selectable marker, a terminator, and a second flanking sequence derived from a plastid sequence, as claimed in the issued patent, are species of the genus of plastid transformation vectors comprising a first flanking sequence, a DNA coding for a foreign



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gene, and a second flanking sequence, and make obvious plants transformed therewith, as claimed in the current application.

21. Claims 1-9, 11-12, 15-23, 25-27, 30-33 and 35-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29-55 of copending Application No. 11/190,122.

Although the conflicting claims are not identical, they are not patentably distinct from each other because expression cassettes for plastid transformation, comprising a first flanking sequence derived from a plastid sequence, a plastid promoter, a selectable marker, a second promoter, a second selectable marker, a terminator (including psbA 3'), and a second flanking sequence derived from a plastid sequence, wherein the selectable markers include those that confer resistance to kanamycin, plants transformed therewith, and methods of using them in a plastid transformation methods that involves somatic embryogenesis, as claimed in the copending application, are species of the genus of plastid transformation vectors comprising a first flanking sequence, a DNA coding for a foreign gene, and a second flanking sequence, and plants transformed therewith, and methods of using them in a plastid transformation methods that involves somatic embryogenesis, as claimed in the current application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

22. Claims 1, 11-12, 17-26, 30, 33, 35-36-37 and 39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21, 28-30 and 32-34 of copending Application No. 10/519,820.

Although the conflicting claims are not identical, they are not patentably distinct from each other because plastid transformation vectors comprising a first flanking sequence, a DNA coding for IGF-1, and a second flanking sequence, wherein the flanking sequences are homologs to a plastid spacer region, as claimed in the copending application, are species of the genus of plastid transformation vectors comprising a first flanking sequence, a DNA coding for a foreign gene, and a second flanking sequence, as claimed in the current application. Dependent claims of both specify antibiotic free selectable markers, like BADH, and antibiotic selectable markers, like aadA, as well as plants and plant cells transformed with the vector.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

23. No claim is allowed.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, Ph.D., whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

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August 7, 2009

/Anne R Kubelik/

Primary Examiner, Art Unit 1638